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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,298	03/09/2004	Masato Mitsuhashi	HITACH.055CP2	9108

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,298	MITSUHASHI, MASATO	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/5/2004, 7/5/2005, and 2/13/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-75 and 77-214* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-75 and 77-214* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1. The Preliminary Amendments filed on August 5, 2004, July 5, 2005, and February 16, 2006 have been entered. The pending claims in this application is 1, 3-75, and 77-214.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-38, 73-75 and 77-93, drawn to a method of high throughput quantification of a specific mRNA in whole blood (claims 1 and 3-38) and a method of determining a definite quantity of target mRNA in a blood sample (claims 73-75 and 77-93), classified in class 435, subclass 6.

II. Claims 39-44, drawn to a high throughput mRNA quantification device (claims 39-44), a lysis buffer (claims 45-65), and a high throughput mRNA quantification kit (claim 66-70), classified in class 435, subclass 287.2 and class 436, subclass 18.

III. Claim 71, drawn to a method of lysing cells, classified in class 436, subclass 522.

IV. Claim 72, drawn to a method of determining a definite quantity of leukocyte specific mRNA per μL of whole blood, classified in class 435, subclass 6.

V. Claims 94-135, drawn to a method of synthesizing cDNA (claims 94 and 95), and a method for quantifying a first specific mRNA (claims 96-135),

classified in class 435, subclass 6.

VI. Claims 136-187, drawn to a method of detecting mRNA indicative of a cellular response to a bioagent, classified in class 435, subclass 6.

VII. Claims 188-213, drawn to a method of identifying an individual expressing abnormal levels of mRNA, classified in class 435, subclass 6.

VIII. Claim 214, drawn to a method of isolating mRNA from a cell lysate, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group V.

Group I and Groups III to VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as step (g) of claim 73is not required for Groups III to VIII while the search required for Group III such as the lysis buffer in claim 71 or the search required for Group IV such as determining a definite quantity of leukocyte specific mRNA per μL of whole blood in claim 72 or the search required for Group V such as step e) in claim 96 or the search required for Group VI such as step g) in claim 136 or the search required for Group VII

such as step j) in claim 188 or the search required for Group VIII such as maintaining step in claim 214 is not required for Group I.

Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group V.

Group III and Groups IV to VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as the lysis buffer in claim 71 is not required for Groups IV to VIII while the search required for Group IV such as determining a definite quantity of leukocyte specific mRNA per μL of whole blood in claim 72 or the search required for Group V such as step e) in claim 96 or the search required for Group VI such as step g) in claim 136 or the search required for Group VII such as step j) in claim 188 or the search required for Group VIII such as maintaining step in claim 214 is not required for Group III.

Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group V.

Group IV and Groups V to VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as determining a definite quantity of leukocyte specific mRNA per μL of whole blood in claim 72 is not required for Groups V to VIII while the search required for Group V such as step e) in claim 96 or the search required for Group VI such as step g) in claim 136 or the search required for Group VII such as step j) in claim 188 or the search required for Group VIII such as maintaining step in claim 214 is not required for Group IV.

Groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group I.

Group V and Groups VI to VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as step e) in claim 96 is not required for Groups VI to VIII while the

search required for Group VI such as step g) in claim 136 or the search required for Group VII such as step j) in claim 188 or the search required for Group VIII such as maintaining step in claim 214 is not required for Group V.

Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group I.

Group VI and Groups VII and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VI such as step g) in claim 136 is not required for Groups VII and VIII while the search required for Group VII such as step j) in claim 188 or the search required for Group VIII such as maintaining step in claim 214 is not required for Group VI.

Groups II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group I.

Groups VII and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VII such as step j) in claim 188 is not required for Groups VIII while the search required for Group VIII such as maintaining step in claim 214 is not required for Group VII.

Groups II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method recited in Group I.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Group I contains claims directed to the following patentably distinct species:

(1) the transfer of lysate to the oligo(dT)-immobilized plate comprises centrifugation (claims 12 and 88)

(2) the transfer of lysate to the oligo(dT)-immobilized plate comprises vacuum aspiration (claims 13 and 89)

(3) the transfer of lysate to the oligo(dT)-immobilized plate comprises applying positive pressure (claims 14 and 90)

The species are independent or distinct because these species are directed to different transfer methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1, 3-11, 15-38, 73-75, 77-87, and 90-93.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Group I further contains claims directed to the following patentably distinct species:

(4) the mRNA quantified is β-actin (claim 16)

(5) the mRNA quantified is CD4 (claim 17)

(6) the mRNA quantified is cytokines (claims 28, 34, and 35)

The species are independent or distinct because these species are directed to different genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1, 3-15, 18-27, 29-33, 36-38, 73-75, and 77-93.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Group I further contains claims directed to the following patentably distinct species:

(7) the mRNA of a translocation gene involved in leukemia is quantified (claim 18)

(8) the mRNA of cancer-specific genes from micrometastatic cancer is quantified (claim 19)

(9) virus-derived mRNA from infected white blood cells is quantified (claims 20-26)

(9) the mRNA of apoptosis genes involved in leukemia is quantified (claim 27)

(10) the mRNA of DNA-repair genes is quantified (claims 30 and 31)

(11) the mRNA of allergen response genes is quantified (claims 32 and 33).

The species are independent or distinct because these species are directed to different genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1, 3-17, 28, 29, 34-38, 73-75, and 77-93.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Group V contains claims directed to the following patentably distinct species:

(12) the transfer of lysate to the oligo(dT)-immobilized plate comprises centrifugation (claim 126)

(13) the transfer of lysate to the oligo(dT)-immobilized plate comprises vacuum aspiration (claim 127)

(14) the transfer of lysate to the oligo(dT)-immobilized plate comprises applying positive pressure (claim 128)

The species are independent or distinct because these species are directed to different transfer methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 94-125 and 129-135.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Group VI contains claims directed to the following patentably distinct species:

(15) the transfer of lysate to the oligo(dT)-immobilized plate comprises centrifugation (claims 152 and 178)

(16) the transfer of lysate to the oligo(dT)-immobilized plate comprises vacuum aspiration (claims 153 and 179)

(17) the transfer of lysate to the oligo(dT)-immobilized plate comprises applying positive pressure (claims 154 and 180)

The species are independent or distinct because these species are directed to different transfer methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 136-151, 155-177, and 181-187.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Group VII contains claims directed to the following patentably distinct species:

(18) the transfer of lysate to the oligo(dT)-immobilized plate comprises centrifugation (claim 204)

(19) the transfer of lysate to the oligo(dT)-immobilized plate comprises vacuum aspiration (claim 205)

(20) the transfer of lysate to the oligo(dT)-immobilized plate comprises applying positive pressure (claim 206)

The species are independent or distinct because these species are directed to different transfer methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 188-203 and 207-213.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is

(571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

September 20, 2006

FRANK LU
PRIMARY EXAMINER